

Remarks

This is in response to the September 27, 2010 final Office Action in the above-referenced patent application. This Reply is being submitted within two months of the mailing date of the Office Action. No petition or fee for extension of time is required.

5 **Status of the Claims**

The original claims 1-2, 4-6, 8-22, 24, and 27-43 were pending for purposes of this Office Action. Claims 3, 7, 23, and 25-26 were previously canceled, and claims 6, 11-14, 24, and 27-42 were withdrawn. Claim 1 is currently amended, and claim 4 is canceled. Claims 1-2, 5, 8-10, 15-22, and 43 remain. Reconsideration is respectfully requested.

10 **Obviousness-Type Double Patenting Rejections**

Claims 1-2, 4-5, 8-10, 15-22, and 43 remain rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-20 of US Pat. No. 7,329,418. A Terminal Disclaimer submitted May 11, 2010 was deemed improper because a power of Attorney was not of record. Applicants submit herewith a New Power of Attorney and respectfully request that the Terminal Disclaimer be accepted and entered. Applicants believe the acceptance of the Terminal Disclaimer obviates the obviousness-type double patenting rejection, and respectfully request reconsideration and withdrawal of this rejection.

15 A nonstatutory obviousness-type double patenting rejection of claims 1-2, 4-5, 8-10, 15-22, and 43 is maintained over certain claims in co-pending application U.S. Ser. No. 10/598,267. Applicants submit herewith a Terminal Disclaimer over the '267 application. The Terminal Disclaimer is believed to overcome this obviousness-type double patenting rejection; reconsideration and withdrawal of this rejection is respectfully requested.

20 In addition, Claims 1-2, 4-5, 8-10, 15-22, and 43 are newly rejected on the ground of nonstatutory obviousness-type double patenting over certain claims in U.S. Ser. No. 11/569,343. Applicants further submit herewith a Terminal Disclaimer over the '343 application, which is believed to overcome this obviousness-type double patenting rejection; withdrawal of this rejection is respectfully requested upon reconsideration.

Prior Art Rejections

The pending claims stand rejected as being anticipated under 35 USC 102(e) over US Pat. Appl. Pub. No. 2004/0234608 (the “‘608 application”). Applicants respectfully traverse.

5 The claimed invention concerns a segmented tablet wherein all segments – the segments containing active ingredient and the segments containing inactive ingredients – are immediate release formulations. By contrast, the ‘608 application concerns a Gastric Retention Delivery System (GRDS) dosage form having an inactive portion, or “reservoir,” which is not an immediate release (IR) formulation. Only the active ingredient-containing portion of the dosage form described in the ‘608 application can be
10 an IR formulation.

The claimed invention is further distinguished from the dosage forms described in the ‘608 application in that it comprises an IR inactive segment that is adapted to be broken for dividing the dose prior to administration. The swellable (inactive) portion of the dosage form described in the ‘608 application, (which, again, is not an IR formulation) is provided to facilitate gastric retention of the dosage form, allowing delivery of the active ingredient while the dosage form is in the stomach. The IR, inactive (swellable) portion of the dosage form described in the ‘608 application is not intended to be broken for dividing the dose prior to administration of the tablet, and would lose its full gastric retentive function if broken prior to administration.
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20 In view of the above distinctions between the claimed invention and the cited ‘608 application, a rejection under 35 USC 102, citing a reference that does not anticipate each and every element of the claimed invention, cannot stand. Accordingly, applicants respectfully request reconsideration and withdrawal of the rejection under 35 USC 102(e) in view of US Pat. Appl. Pub. No. 2004/0234608.

25 The pending claims also stand rejected as being anticipated under 35 USC 102(b) over PCT Publication No. WO 00/18447 (the “WO’447 application”). Applicants respectfully traverse this rejection as well.

WO'447 concerns an inactive portion (enveloping active tableted cores) which is provided as an extended release formulation. Administration of the tablet as described in the WO'447 application would provide controlled release of the actives – even from the immediate release (IR) tablet cores contained within the extended release inactive portion.

5 Accordingly, the tablet described in the WO'447 application is a controlled release tablet.

Because the claimed invention is directed solely to an IR tablet, and expressly recites a tablet having a segment which “comprises an immediate release inactive composition,” the cited WO '447 application does not anticipate the claims of the subject application. Withdrawal of the rejection under 35 USC 102(b), citing PCT Publication No. WO
10 00/18447, is respectfully requested upon reconsideration.

The Office Action further rejects certain of the claims under 35 USC 103(a) as being obvious over the '608 application in view of the WO'447 application. This obviousness rejection is based on the inaccurate premise that the '608 application describes layered tablets having an immediate release inactive portion and that the WO'447 application describes an immediate release inactive portion, which can be scored. However, a close review of the cited references shows that neither the '608 nor WO'447 applications teach or otherwise suggest tablets having inactive portions that are IR formulations, as claimed.
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The '608 application includes inactive portions that are swellable (e.g., a hydrogel) formulations for controlling release of active by keeping the dosage form within the stomach during release of drug. Thus, the '608 application is defective in its teaching regarding an IR inactive portion of the tablet.
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The WO'447 application describes IR formulations but, like the '608 application, describes such formulations for the *active* portions only. The inactive portion of the tablet described in the WO'447 application is always a controlled release formulation (see, e.g., p.1, lines 8-10 reciting “two immediate release compartments substantially enveloped by a [an inactive] scored extended-release compartment.”) No teaching or suggestion is present in WO'447 of an inactive portion that is formulated as an IR composition, and the WO'447 application fails to cure the defect of the '608 application.
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Because neither of the cited references teach or suggest a tablet as claimed – i.e., a completely IR tablet having IR inactive and IR active segments, applicants respectfully submit that the claimed invention would have been unobvious in view of either reference, separately, or both references combined. Reconsideration and withdrawal of the rejection under 35 USC 103(a) citing the ‘608 and WO’447 applications is respectfully requested.

5 Certain of the claims are also rejected under 35 USC 103(a) as being obvious over the ‘608 application in view of the WO’447 application, and US Patent No. 4,509,589 (the “‘589 patent”). The ‘608 and WO’447 applications are deficient in their teachings against the subject invention as described above. The ‘589 patent, which is cited merely for its
10 description of printed indicia as separation marks, does not cure the defects of the ‘608 and WO’47 applications, taken together or alone. Because these cited references, separately and combined, fail to teach or suggest the claimed invention, applicants respectfully submit that the claimed invention would not have been obvious in view thereof. Reconsideration and withdrawal of the rejection under 35 USC 103(a) citing the
15 ‘608 application, in view of the WO’447 application and the ‘589 patent is respectfully requested.

Certain of the claims are further rejected under 35 USC 103(a) as being obvious over EP 0348683 (the “EP’683 application”) and the WO’447 application, in view of Pharmaceutical Industry Info 2002 (PII2002) and further in view of US Patent Nos.
20 5,118,021 (the “‘021 patent”) and 4,509,589 (the “‘589 patent”).

The EP’683 application describes a three layer tablet having an inactive layer for separating incompatible actives in the other two layers. This reference is therefore inapposite to the two-layer claimed tablets. With regard to three-layer tablets of the subject invention, the EP’683 application fails to describe a tablet having a middle inactive layer that is greater in height than the combined height of the active layers, as claimed. Specifically, the EP’683 application describes an inactive middle layer that is no more than 40% of the height of the tablet. By definition, a tablet of the subject invention has a middle layer greater than 50% of the total tablet height.

This distinction has importance in the way the tablets are used. Tablets described in the EP'683 application have a middle layer provided solely to separate incompatible actives. In tablets of the subject invention, the middle inactive layer is adapted to be broken for dividing the dose prior to administration. The concept of dose division by breaking the
5 middle layer is not taught or suggested by the EP'683 application. The inclusion of the inactive middle layer in tablets of the EP'683 application is to provide a combination product where the two actives can be administered together, and not divided prior to administration.

The WO'447 application is deficient in its teachings against the subject invention as
10 described above. In further contrast to the assertion presented in the Office Action, the WO'447 application does not describe a tablet having an inactive layer that is greater in height than combined height of the active layers. First, it is noted that the three-layer tablets of the subject invention have a total height greater than their total width. As defined and supported in the specification, the height of the tablet refers to the vertical
15 measurement while the tablet is in the tablet die, and prior to ejection from the die. Tablets of the WO'447 application are formed in a die having 5/16" height and 3/4" width – clearly having a width greater than height. Accordingly, applicants respectfully submit that the WO'447 application does not teach or suggest the claimed tablets, nor does the WO'447 application cure the defect of the EP'683 application.

20 The Office Action cites the 2002 Pharmaceutical Industry Info. reference (2002 PII), disclosing the Korsch TRP 700/900, apparently for its teaching of a taller-than-wide tablet. However, applicants respectfully submit that the 2002 PII reference does not cure the defect of EP '683. Indeed, even when combined, the EP '683 and 2002 PII references still fail to teach or suggest an
25 IR layered tablet having a middle inactive segment which advantageously serves as a discrete breaking layer or segment.

The 2002 PII reference discloses the Korsch multilayer tablet press – a device and process accepted in the art as useful for manufacturing controlled-release (CR) tablets. Specifically, the Korsch tablet press provided for the manufacture of a tablet having an expandable “push layer” which enabled the release of a drug to be modified. These push layers expand when contacted by
30 aqueous solution to force solubilized active ingredients (in a separate layer) through an opening in

the tablet coating. These coatings are typically insoluble in the aqueous solution in order to provide a relatively rigid surface against which to “push” and provide the force for excreting the drug composition. Moreover, these inactive push layers were provided at one end of the tablet, not between two active layers, and were not intended to be broken through in order to divide the dose or doses provided in the whole tablet as claimed for the subject invention. Applicants believe there is no reasonable nexus between the IR layered tablets of EP ‘683 and the manufacturing device and process for manufacturing CR tablets containing a “push layer” as described in the 5 2002 PII reference.

The inactive push layer in tablets manufactured in accordance with the PII 2002 reference was not intended to be broken through in order to divide the dose or doses in the whole tablet, as claimed for the subject tablet. Because of the rigid coating required on a tablet made by the process contemplated by the PII 2002 reference, conventional breaking techniques, such as breaking by hand, make it difficult if not practically impossible to break through the tablets. Also, breaking through an inactive push layer of the prior art “controlled-release” tablets 10 15 can render such tablets inoperable. Accordingly, applying or combining the knowledge of using a Korsch multilayer tablet press with the layered immediate release tablets of EP ‘683 goes completely against the teaching of the subject invention

Thus, other than the impermissible use of applicants’ own disclosure as a basis for hindsight reconstruction of the claimed invention, the motivation to combine these two cited references and 20 their combined teaching or suggestion of the claimed invention appear to be absent. Applicants respectfully maintain that nowhere in EP ‘683 or the 2002 PII references is there any disclosure directing or motivating a person of ordinary skill in the art toward the specific active/inactive/active taller-than-wide configuration in a three-layer, immediate-release tablet as expressly claimed. And nowhere in EP ‘683 or the 2002 PII reference is there any disclosure 25 directing or motivating a person of ordinary skill in the art toward a tablet which provides the specific advantages achieved by the claimed tablet configuration.

The claimed invention as a whole, and as currently claimed, provides unique properties which 30 were unavailable from the tablets described in the cited references. These unique properties of the claimed invention further provide unique advantages that were unforeseen by persons of ordinary skill in the art having access to, or knowledge of, the cited references.

The “taller-than-wide” configuration of the claimed tablets (as it sits in the compression die) lends itself to having the vertical axis as its long axis. By having an inactive segment between two active segments in a taller-than-wide tablet, as claimed, the inactive segment can advantageously be useful as a breaking segment. This provides that the area around the midline of the vertical axis is the most advantageous area for breaking the tablets in half – and through the inactive middle segment – such that no breakage occurs to the active end segments.

Because breakage will occur easiest “across” the short axis of the tablet, the claimed taller-than-wide tablet can break through a single layer, i.e., the inactive segment. Breakage in this manner allows physical separation of the active “end” segments from one another without breaking through any part of those active segments. Therefore, the active segments can remain intact even after the whole tablet is divided into two or more portions. This feature can advantageously prevent any loss of active during the breaking of the tablet. The standard wider-than-tall tablet, as known in the art, cannot provide this advantage, even if it includes an inactive segment between two active segments because the short axis is oriented “across” the layers.

Advantageously, the claimed invention, having an inactive middle segment as its breaking segment, allows the tablet to be broken so that the break is confined to that inactive segment. In such case, there is no breakage through any portion containing active substance, thus preventing loss of active ingredient from any resulting tablet portion, even when the broken edges (of the inactive segment) may chip or crumble.

The innovation arrived at for the subject taller-than-wide tablets originated from the unique motivation to provide a tablet readily breakable into precise partial doses and thereby allowing flexible dose adjustment and titration under a single prescription and a single visit to the physician. Applicants have therefore developed an entirely new compressed tablet configuration which addresses an unmet need.

The secondary'021 and '589 patents are apparently cited for their description of separation marks, including printed indicia, in the tablets. However, neither of these secondary references cure the defects of the EP'683 or WO'447 applications, or the PII2002 reference. Because these cited references, separately and combined, fail to teach or suggest the claimed invention, applicants respectfully submit that the claimed invention would not have been obvious in view thereof. Reconsideration and withdrawal of the

rejection under 35 USC 103(a) citing the EP'683 application and the WO'447 application, in view of PII2002 and further in view of the '021 and the '589 patents is respectfully requested.

5 Applicants believe that the pending claims, as amended, are in condition for allowance and respectfully request issuance of a Notice of Allowance.

Applicants invite the Examiner to contact the undersigned at the address and/or phone number provided below if clarification or additional information is needed on any of these matters.

Respectfully submitted,

10 Dated: November 29, 2010 /Ted W. Whitlock/

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